

105TH CONGRESS  
1ST SESSION

# H. R. 2250

To amend section 353 of the Public Health Service Act to exempt physician office laboratories from the clinical laboratories requirements of that section.

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## IN THE HOUSE OF REPRESENTATIVES

JULY 24, 1997

Mr. ARCHER (for himself, Mr. GOSS, Mr. LIVINGSTON, Mr. SPENCE, Mr. STUMP, Mr. YOUNG of Alaska, Mr. SPRATT, Mr. TALENT, Mr. STENHOLM, Mr. CRANE, Mr. HEFNER, Mr. FROST, Mr. PORTER, Mr. HALL of Texas, Mr. HANSEN, Mr. MCCOLLUM, Mr. SHAW, Mr. SKEEN, Mrs. JOHNSON of Connecticut, Mr. OXLEY, Mr. BARTON of Texas, Mr. COMBEST, Mr. GORDON, Mr. DUNCAN, Mr. MCCRERY, Mr. PICKETT, Mr. NEAL of Massachusetts, Mr. STEARNS, Mr. TANNER, Mr. WALSH, Mr. DOOLEY of California, Mr. CAMP, Mr. CRAMER, Mr. CUNNINGHAM, Mr. SAM JOHNSON of Texas, Mr. KLUG, Mr. EHLERS, Mrs. FOWLER, Mr. HOLDEN, Mr. LEWIS of Kentucky, Ms. PRYCE of Ohio, Mrs. THURMAN, Mr. BALDACCI, Mrs. CHENOWETH, Mr. COBURN, Mrs. CUBIN, Mr. EHRLICH, Mr. ENGLISH of Pennsylvania, Mr. ENSIGN, Mr. FOLEY, Mr. GANSKE, Mr. MCINTOSH, Mr. NETHERCUTT, Mr. NORWOOD, Mr. SHADEGG, Mr. THORNBERRY, Mr. SESSIONS, Mr. BURTON of Indiana, Mr. SAXTON, and Mr. GILLMOR) introduced the following bill; which was referred to the Committee on Commerce

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## A BILL

To amend section 353 of the Public Health Service Act to exempt physician office laboratories from the clinical laboratories requirements of that section.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2       This Act may be cited as the “Clinical Laboratory  
3 Improvement Act Amendments of 1997”.

4 **SEC. 2. EXEMPTION OF PHYSICIAN OFFICE LABORATORIES.**

5       Section 353(d) of the Public Health Service Act (42  
6 U.S.C. 263a(d)) is amended—

7           (1) by redesignating paragraphs (2), (3), and  
8           (4) as paragraphs (3), (4), and (5) and by adding  
9           after paragraph (1) the following:

10           “(2) EXEMPTION OF PHYSICIAN OFFICE LAB-  
11           ORATORIES.—

12                   “(A) IN GENERAL.—Except as provided in  
13                   subparagraph (B), a clinical laboratory in a  
14                   physician’s office (including an office of a group  
15                   of physicians) which is directed by a physician  
16                   and in which examinations and procedures are  
17                   either performed by a physician or by individ-  
18                   uals supervised by a physician solely as an ad-  
19                   junct to other services provided by the physi-  
20                   cian’s office is exempt from this section.

21                   “(B) EXCEPTION.—A clinical laboratory  
22                   described in subparagraph (A) is not exempt  
23                   from this section when it performs a pap smear  
24                   (Papanicolaou Smear) analysis.

25                   “(C) DEFINITION.—For purposes of sub-  
26                   paragraph (A), the term ‘physician’ has the

1 same meaning as is prescribed for such term by  
2 section 1861(r) of the Social Security Act (42  
3 U.S.C. 1395x(r)).”;

4 (2) in paragraph (3) (as so redesignated) by  
5 striking “(3)” and inserting “(4)”; and

6 (3) in paragraphs (4) and (5) (as so redesign-  
7 nated) by striking “(2)” and inserting “(3)”.

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